

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS**

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**IN RE: YASMIN AND YAZ (DROSPIRENONE)  
MARKETING, SALES PRACTICES AND PRODUCTS  
LIABILITY LITIGATION**

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) **3:09-md-02100-DRH-  
) PMF  
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) MDL No. 2100**

**This Document Relates to:**

***Bradish v. Bayer Healthcare  
Pharmaceuticals Inc., et al.*, 09-20021-DRH-PMF**

**MEMORANDUM AND ORDER**

**I. Introduction and Background**

Now before the Court is defendants' motion to exclude plaintiffs' case specific expert testimony and for partial summary judgment (Doc. 46). Plaintiff opposes the motion (Doc. 58). Familiarity with the underlying proceedings is presumed. Although the motion is fully briefed, the Court holds in abeyance the portion of the motion regarding summary judgment until after the resolution of the trial in *Sims v. Bayer Healthcare Pharmaceuticals Inc., et al.*, 09-10012-DRH-PMF. Based on the pleadings, the applicable law and the following, the Court denies the motion to exclude plaintiff's expert.

This multidistrict litigation “(MDL)” relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.<sup>1</sup> YAZ and Yasmin, which are manufactured, marketed, and sold by Bayer, are members of a class of prescription medicines known as combined hormonal oral contraceptives (“COCs”), which contain an estrogen and a progestin component. The vast majority of COC’s, including YAZ and Yasmin, contain the same type of estrogen – ethinyl estradiol (“EE”). *Id.*<sup>2</sup> In contrast to estrogen, the progestins in COCs are of many types. The progestin in YAZ and Yasmin is a newer type of progestin known as drospirenone (“DRSP”). *Id.*

DRSP-containing COCs are known as “fourth-generation” COCs (classified by the type of progestin used). *Id.* at pp. 6-5. COCs containing earlier developed progestins are categorized as “first-generation,” “second-generation,” and “third-generation.” *Id.* at p. 6. First-generation COCs contain the progestin norethynodrel. *Id.* Second-generation COCs contain the progestin Levonorgestrel (“LNG”) and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate. *Id.*

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<sup>1</sup>This MDL relates to other oral contraceptives that, like YAZ and Yasmin, contain drospirenone. However, YAZ and Yasmin are the subject drugs involved in the pending bellwether trials.

<sup>2</sup>YAZ and Yasmin differ in their dosing schedule and the amount of estrogen they contain. The Food and Drug Administration (“FDA”) approved YAZ and Yasmin as oral contraceptives in 2006. The FDA subsequently approved YAZ and Yasmin as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive and as a treatment for premenstrual dysphoric disorder (“PMDD”) in women who choose to use an oral contraceptive.

It is generally accepted that there is an increased risk of venous thromboembolic (“VTE”) disease (disease relating to blood clotting in the veins) in COC users. It is also generally accepted that second-generation COCs (LNG-containing COCs) are considered to have a low risk for VTE disease. Because the VTE risk associated with second-generation COCs is relatively low, LNG-containing COCs are often selected as a reference treatment in comparative studies evaluating whether there is an association between third-generation COCs and an increased risk of VTE disease and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease . In the mid-1990s, various reports indicated that users of third-generation COCs were at higher risk of VTE disease than users of second-generation COCs.

At issue in this litigation, is the safety of DRSP-containing COCs and whether DRSP use is associated with a higher risk of VTE disease. Specifically, Plaintiffs contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With regard to the safety of YAZ and Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life threatening thrombosis complications, including deep vein thrombosis (“DVT”) (a blood clot formation in one of the body’s deep veins) and pulmonary embolism (“PE”) (a clot formation that travels to the lungs).

In the case at bar, plaintiff, Patti Bradish, was given a sample pack of YAZ in February of 2007. At some point between February and May 2007 Mrs. Bradish used the sample pack of YAZ. In May 2007, Mrs. Bradish received a prescription for YAZ and began using YAZ as her method of birth control. Six months later Mrs. Bradish visited her primary care physician's office complainint of pain in her left leg. Laboratory and diagnostic testing was ordered, and she was instructed to discontinue her use of YAZ. The laboratory results showed significantly elevated D-dimer levels, which can indicate a blood clot. Mrs. Bradish was eventually diagnosed with bilateral pulmonary emboli and "probable acute bilateral" DVT.

Bayer moves to exclude the opinions of plaintiffs' expert, Dr. Henry Rinder. Bayer contends that Dr. Rinder's opinions fail to meet the requirements for admissible expert testimony under Federal Rule of Evidence 702 and *Daubert v. Merrill Dow Pharms.*, 509-UC 579 1993 (*Daubert*). Specifically, Bayer seeks to preclude testimony by Dr. Rinder regarding Mrs. Bradish's alleged damages and prognosis as speculative and unfairly prejudicial.

## **II. Legal Standard**

FEDERAL RULE OF EVIDENCE 702, and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), govern the admissibility of expert testimony. The *Daubert* standard applies to all expert testimony, whether based on scientific competence

or other specialized or technical expertise. *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526

U.S.137, 141 (1999)). Rule 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. *Daubert* clarified Rule 702 charges the district court with the task of ensuring expert testimony is both relevant and reliable. *Daubert*, 509 U.S. at 589.

Courts in the Seventh Circuit conduct a three-step analysis under *Daubert*. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007).<sup>3</sup> First, the district court must determine whether the person whose testimony is offered is in fact an expert, as codified in Rule 702 through “knowledge, skill, experience, training, or education.” *Id.* (citing Fed. R. Evid. 702). Notably, although “extensive academic and practical expertise” sufficiently qualify a potential witness as an expert, *Bryant v. City of Chicago*, 200 F.3d 1092, 1098 (7th Cir. 2000), “Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience,” *Walker v. Soo Line R.R. Co.*, 208 F.3d 581,

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<sup>3</sup>The Court notes the Seventh Circuit has also described the *Daubert* analysis as a two-step process. See *Chapman v. Maytag Corp.*, 297 F.3d 682, 686 (7th Cir. 2002). However, as *Chapman* simply combines the first two steps described in *Ervin* as a single test of reliability, whether the analysis is described as a three-step or two-step process does not substantively change the Court’s analysis.

591 (7th Cir. 2000). *Smith*, 215 F.3d at 718 (citing *Kumho*, 526 U.S. at 156 (“[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.”)).

Secondly, the district court must determine the expert’s reasoning or methodology is reliable. *Ervin*, 492 F.3d at 904; *see Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir. 2004) (citing *Kumho*, 526 U.S. at 147). Specifically, the testimony must have a reliable basis in the knowledge and experience of the relevant discipline, *Kumho*, 526 U.S. at 149 (internal quotations removed), consisting in more than subjective belief or unsupported speculation. *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002); *Daubert*, 509 U.S. at 590.

Further, as to reliability, *Daubert* provided the following non-exhaustive list of relevant factors: “(1) whether the scientific theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory has been generally accepted in the scientific community.” *Ervin*, 492 F.3d 901, 904 (7th Cir. 2007) (citing *Daubert*, 509 U.S. at 593-94). However, there is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be “tied to the facts” of the particular case. *Kumho*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 591); *see also Chapman*, 297 F.3d at 687. Thus, “the role of the court is to determine whether the expert is qualified in the relevant field and to examine the methodology the expert has used in reaching his [or her] conclusions.” *Smith*, 215 F.3d at 718 (citing *Kumho*, 526 U.S. at 153).

The district court possesses “great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable.” *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) (citing *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007)).

Accordingly, the court’s gatekeeping function requires focus on the expert’s methodology; “[s]oundness of the factual underpinnings of the expert’s analysis and the correctness of the expert’s conclusions based on that analysis are factual matters to be determined by the trier of fact.” *Smith*, 215 F.3d at 718 (citing *Daubert*, 509 U.S. at 595; *Walker*, 208 F.3d at 587).

Resolution of an expert’s credibility or the correctness of his or her theories is left to the jury’s determination after opposing counsel has cross-examined the expert at issue. *Id.* (citing *Walker*, 208 F.3d at 589-90). Thus, “[i]t is not the trial court’s role to decide whether an expert’s opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound.” *Id.* (citing *Kumho*, 526 U.S. at 159 (Scalia, J., concurring) (stating that the trial court’s function under *Daubert* is to exercise its discretion “to choose among reasonable means of excluding expertise that is *fausse* and science that is *junky*”)). However, as an expert must explain the methodologies and principles that support his or her opinion, he or she cannot simply assert a “bottom line” or *ipse dixit* conclusion. *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) (quoting *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010)).

Lastly, the district court must consider whether the proposed testimony will assist the trier of fact in its analysis of any issue relevant to the dispute. See *Smith*, 215 F.3d at 718; *Chapman*, 297 F.3d at 687; *Daubert*, 509 U.S. at 592. It is crucial that the expert “testify to something more than what is ‘obvious to the layperson’ in order to be of any particular assistance to the jury.” *Dhillon v. Crown Controls Corp.*, 269 F.3d 865, 871 (7th Cir. 2001) (quoting *Ancho v. Pentek Corp.*, 157 F.3d 512, 519 (7th Cir. 1998)). However, the expert need not have an opinion as to the ultimate issue requiring resolution to satisfy this condition. *Smith*, 215 F.3d at 718 (citing *Walker*, 208 F.3d at 587).

Indisputably, a medical degree does not qualify a doctor to opine on all medical subjects. *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (citing *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212 (7th Cir. 1990)). However, the Seventh Circuit recognizes that often a “physician in general practice is competent to testify about problems that a medical specialist typically treats.” *Id.* (citing 29 Wright & Gold, Federal Practice and Procedure, § 6265 (1997); *Doe v. Cutter Biological, Inc.*, 971 F.2d 375, 385 (9th Cir. 1992) (“The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor.”); *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 978-79 (6th Cir. 2004); *United States v. Viglia*, 549 F.2d 335, 336 (5th Cir. 1977) (holding that a pediatrician who had

degrees in medicine and pharmacology but no experience in treating patients in obesity had sufficient knowledge, training, and education to testify regarding drug's effect on obese persons)). Thus, courts must individually evaluate each conclusion drawn to determine whether the purported expert "has the adequate education, skill, and training to reach them."

### **III. Analysis**

Defendants move to exclude the opinions of Dr. Henry Rinder regarding plaintiff's alleged damages and prognosis. Defendants contend that the Court should exclude Dr. Rinder's damages opinions as speculative in that these opinions are not based on a diagnosis of a current medical condition or one that is more likely than not to occur in the future. Specifically, defendants contend that Dr. Rinder offers many damages opinions that should be excluded as speculative. In their motion, defendants identify the following as improper speculative opinions that should be excluded:

1) Dr. Rinder's report opines that Mrs. Bradish "was required to undergo tubal ligation because of [her] contraindication for COC's." Doc. 46 p. 9).

With regard to this opinion, Defendants state that Dr. Rinder admitted that he is "not an expert enough in that area to know whether that was something that was purely elective or whether that was forced on her by the situation. I can't comment as to that." *Id.*

2) Dr. Rinder's report opines that Mrs. Bradish "is at risk for post-thrombotic syndrome." *Id.*

3) Dr. Rinder's report states that Mrs. Bradish is "at increased future risk of recurrent VTE," which could be fatal. *Id.* at p. 10. Dr. Rinder further opined that, if Mrs. Bradish suffered another VTE, "she would likely be

placed on life-long anticoagulation with all of its attendant risks and lifestyle issues.” *Id.*

Post-thrombotic syndrome is characterized by chronic, persistent pain, swelling, and other signs in the affected limbs. Rinder Dep. (Ex. H) at 131:3-132:1. It has been four years since Mrs. Bradish was diagnosed with her PE/DVT, *see* Medical Records (Ex. C) at PPR-84-85. Defendants state that Dr. Rinder has “not found evidence that [Mrs. Bradish] has developed post-thrombotic syndrome.” *Id.* at 132:3-11. Moreover, defendants contend he “cannot say, more likely than not, [that] she will develop postthrombotic syndrome” in the future. *Id.* at 135:18-136:5.

Plaintiff counters that defendants distort and mischaracterize Rinder’s statements as opinions regarding future damages. Plaintiff posits that Rinder’s opinions are not that plaintiff will more likely than not develop future clots, but that as a result of defendants’ conduct, she has a lifelong, increased risk for subsequent clots and post-thrombotic syndrome that she did not have prior to the injury resulting from her YAZ use. The Court agrees with plaintiff.

Dt. Rinder is an attending physician in hematology and laboratory medicine at Yale-New Haven Hospital. Dr. Rinder’s clinical practice over the past 19 years has included the diagnosis and treatment of VTE disease which includes DVT, PE, and cerebral vein (sinus) thrombosis. He has diagnosed and treated hundreds, if not thousands of patients with VTE.

Dr. Rinder is also a Professor of Laboratory Medicine and Internal Medicine (Hematology) at Yale University. Dr. Rinder’s research at Yale University has been

concerned with the science of blood clotting and bleeding. Aside from research and clinical practice, Dr. Rinder teaches hematology to medical students, physician assistant students, residents, and fellows throughout the Yale-New Haven Health System and other Yale University School of medicine affiliated training programs.

Dr. Rinder has written multiple textbook chapters on thrombosis and bleeding, and is one of the editors of the text "Hematology in Clinical Practice." In the past ten years, Dr. Rinder has published two peer-reviewed articles based on his original research. Dr. Rinder has also authored or co-authored more than sixty articles addressing various topics associated with his area of expertise in numerous scientific and clinical journals.

As to plaintiff, Dr. Rinder opined:

In light of the foregoing, it is my opinion to a reasonable degree of medical certainty that Yaz was a substantial factor in causing her VTE event.

The consequences of Ms. Bradish's DVT and PE are significant. She has evidence of significant lung vascular injury as noted by the mitral valve regurgitation. She has an IVC filter permanently placed with its risks of back-pressure venous insufficiency and development of venous thrombosis below (distal to) the filter. She was required to undergo tubal ligation because of the contraindication for COCs, as well as an endometrial ablation procedure because of the complication of endometrial bleeding due to anticoagulation.

She is at risk for post-thrombotic syndrome, and she has objective evidence of increased risk for this entity based on her ultrasound results of reflux in the left lower extremity veins. She is also at increased future risk of recurrent VTE based on: 1) the VTE event suffered; 2) the damaged lower extremity veins; and 3) the permanent IVC filter.

It is important to note that although an IVC filter was placed to prevent pulmonary emboli from clots forming below (distal to) the filter, it is not perfect at prevention, and clots can form on its proximal surface and travel to the lungs. In Ms. Bradish's case, any subsequent PE could be fatal, which is why if she were to suffer any future VTE event, even a DVT below the filter, she would likely be placed on life-long anticoagulation with all of its attendant risks and lifestyle issues.

(Doc. 58-12).

Clearly, Dr. Rinder is qualified to testify as to plaintiff's development of an increased risk of future thromboembolic events and plaintiff's damages suffered by her as a result of her DVTs and PEs. Specifically, the increase of future recurrent DVT or PE that she presently faces will increase during periods of increased risk. As stated previously, Dr. Rinder is a medical doctor with 19 years of clinical experience. Thus, the Court finds he is qualified to opine, within a reasonable degree of medical certainty, concerning the future damages associated with plaintiff's injuries.

As also stated previously, Dr. Rinder bases his opinions concerning plaintiff's future damages on relevant medical literature, plaintiff's medical records, his generic expert report prepared for this litigation, clinical study reports, and his years of experience. Contrary to Bayer's assertion, these opinions are not speculative as Dr. Rinder bases his opinions on his experiences with patients who have suffered PEs. The Court finds that Dr. Rinder has opined within a reasonable degree of medical certainty that plaintiff is at an increased risk of the particular injuries at issue. As such, his opinion is not speculative.

Thus, as Dr. Rinder bases his opinion on a reliable methodology;

specifically, his experience and relevant medical knowledge, the Court finds his opinions as to plaintiff's prognosis, including her possible future harm, and damages admissible. Finally, the probative value of these statements is not outweighed by their prejudicial effect.

#### **IV. Conclusion**

Accordingly, the Court **DENIES** defendants' motion to exclude plaintiffs' case-specific expert testimony (Doc. 46). As noted previously, defendants' partial summary judgment motion remains pending and is held in abeyance until the resolution of the trial in *Sims v. Bayer Healthcare Pharmaceuticals, Inc., et al.*, 09-10012-DRH-PMF.

**SO ORDERED**

 David R. Herndon  
2011.12.16  
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**Chief Judge**  
**United States District Court**

**Date: December 16 2011**